

Atty. Docket No.:

20200/2093D

**PATENT** 

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Kreutzer, et al.

Serial No.:

10/612,179

Filed:

July 2, 2003

Entitled:

METHOD AND MEDICAMENT

FOR INHIBITING THE

EXPRESSION OF A GIVEN GENE

Examiner:

Not Yet Assigned

Group Art Unit:

1645

Conf. No.:

5239

## CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.82

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Brenda M. Woods

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## TRANSMITTAL LETTER

Enclosed for filing in the above-identified patent application, please find the following documents:

- 1. Information Disclosure Statement;
- 2. Form PTO-1449;
- 3. Copies of Cited References; and
- 4. Return Post Card.

The Commissioner for Patents is hereby authorized to charge any additional fees or credit any overpayment in the total fees to Deposit Account No. 16-0085, Reference No. 20200/2093D. A duplicate of this transmittal letter is enclosed for this purpose.

Respectfully submitted,

Date: January 8, 2004

Name: Barbara A. Gyure Registration No.: 34,614 Palmer & Dodge LLP 111 Huntington Avenue Boston, MA 02199-7613

Tel: 617-239-0100



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#### CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8a

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# INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§§ 1.56, 1.97 AND 1.98

Dear Sir:

In accordance with the duty of disclosure under 37 CFR § 1.56, Applicants submit this Information Disclosure Statement pursuant to 37 CFR §§ 1.97 and 1.98 in the above-identified application for consideration by the Patent Office.

A copy of a portion of the cited documents were submitted to the U.S. Patent and Trademark Office in the parent application, U.S. Serial No. 09/889,802. Copies of the documents in the list which were not submitted with the parent application are enclosed for the Examiner's convenience. Pursuant to CFR § 1.97(b)(3), because this Statement is being submitted before the first Office Action on the merits, no fee is required.

Applicant does not intend to represent that any of the documents submitted herein are material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicant respectfully requests that the documents submitted herein be considered and made of record in this application.

Date: January 8, 2004

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Name: Barbara A. Gyure Registration No.: 34,614 Palmer & Dodge LLP 111 Huntington Avenue Boston, MA 02199-7613

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USPTO Form 1449 Serial No. Attorney Docket No. Patent and Trademark Office 10/612,179 20200/2093D INFORMATION DISCLOSURE STATEMENT Applicant(s):. Kreutzer et al. Filing Date: July 2, 2003 Group: 1645 U.S. PATENT DOCUMENTS Examiner Patent No. Date Name Class Subclass Filing Date Initial (if appropriate) 2003/0198627 A1 Oct. 23, 2003 424 93.21 1. Arts, et al. Aug. 23, 2002 2. 2003/0190635 A1 Oct. 9, 2003 435 6 McSwiggen Jul. 25, 2002 3. 2003/0180756 A1 Sep. 25, 2003 Shi, et al. 435 6 Nov. 21, 2002 4. 2003/0176671 A1 Reed, et al. Sep. 18, 2003 536 23.1 Feb. 7, 2002 5. 2003/0157030 A1 Aug. 21, 2003 424 46 Davis, et al. Nov. 4, 2002 6. Aug. 7, 2003 2003/0148341 A1 Sin, et al. 6 Nov. 5, 2002 435 7. 2003/0143732 A1 Jul. 31, 2003 Fosnaugh, et al. 435 325 Aug. 20, 2002 8. 2003/0125281 A1 Jul. 3, 2003 Lewis, et al. 514 44 May 28, 2002 9. 2003/0108923 A1 Jun. 12, 2003 Tuschl, et al. 6 435 Sep. 26, 2002 10. Tuschl, et al. 2002/0086356 A1 Jul. 4, 2002 435 69.1 Mar. 30, 2001 11. 6,423,489 B1 Jul. 23, 2002 Anderson, et al. 435 6 May 30, 1995 6,346,398 Feb. 12, 2002 Pavco, et al. 12. 6,355,415 Mar. 12, 2002 Wagner, et al. 13. 6,482,803 Nov. 19, 2002 Ruth, et al. 14. 6,183,959 Feb. 6, 2001 Thompson 15. 6,225,291 May 1, 2001 Lewin, et al. 16. 6,245,560 June 12, 2001 Lisziewicz 17. 6,245,748 June 12, 2001 Wellstein, et al. 18. 6,255,071 July 3, 2001 Beach, et al. 19. 6,057,156 May 2, 2000 Akhtar, et al. 20. 6,071,890 June 6, 2000 Scheule, et al. 21. 6,077,705 June 20, 2000 Duane, et al. 22. June 27, 2000 23. 6,080,851 Pachuk, et al. 6,087,164 July 11, 2000 Hochberg, et al. 24. 6,087,172 July 11, 2000 Veerapaneni, et al. 25. 6,099,823 Aug. 8, 2000 Falb 26.

217 570	& TARY						
27.	6,100,087	Aug. 8, 2000	Rossi, et al.			<del>.</del> .	
28.	6,100,444	Aug. 8, 2000	Frelinger, et al.				
29.	6,107,094	Aug. 22, 2000	Crooke				
30.	5,968,737	Nov. 16, 1999	Ali-Osman, et al.				
31.	5,985,620	Nov. 16, 1999	Sioud				
32.	5,908,779	June 1, 1999	Carmichael, et al.				
33.	5,898,031	Apr 27, 1999	Crooke				
34.	5,891,717	Apr. 6, 1999	Newgard, et al.				
35.	5,866,701	Feb. 2, 1999	Hampel, et al.				
36.	5,864,028	Jan. 26, 1999	Sioud				
37.	5,854,067	Dec. 29, 1998	Newgard, et al.				
38.	5,814,500	Nov. 1998	Dietz				
39.	5,811,300	Nov. 22, 1998	Sullivan, et al.			,	
40.	5,811,275	Nov. 22, 1998	Wong-Staal, et al.				
41.	5,837,510	Nov. 17, 1998	Goldsmith, et al.				
42.	5,824,519	Oct. 20, 1998	Norris, et al				
43.	5,712,257	Jan. 1998	Carter				
44.	5,639,655	June 17, 1997	Thompson, et al.				
45.	5,635,385	June 3, 1997	Leopold, et al.	-			
46.	5,616,459	Apr. 1, 1997	Kramer, et al.				
47.	5,574,142	Nov. 12. 1996	Meyer, Jr., et al.				
48.	5,525,468	June 11, 1996	McSwiggen				
49.	5,496,698	Mar. 5, 1996	Draper, et al.				
50.	5,246,921	Sep. 21, 1993	Reddy, et al				
51.	5,225,347	July 6, 1993	Goldberg, et al.		:		
52.	5,112,734	May 12, 1992	Kramer, et al.				
ATEN	NT DOCUMENTS						
	Document No.	Publication	Country	Class	Subclass	Transla	tion
		Date				YES	NO
53.	DE 101 00 586 C1	April 11, 2002	Deutschland (Germany)	C12N	15/11		X
54.	WO 03/080807 A2	Oct. 2, 2003	PCT	C12N		X	
55.	WO 03/080794 A2	Oct. 2, 2003	PCT	C12N		X	
	27. 28. 29. 30. 31. 32. 33. 34. 35. 36. 37. 38. 39. 41. 42. 43. 44. 45. 46. 47. 48. 49. 50. 51. 52. 54.	27. 6,100,087 28. 6,100,444 29. 6,107,094 30. 5,968,737 31. 5,985,620 32. 5,908,779 33. 5,898,031 34. 5,891,717 35. 5,866,701 36. 5,864,028 37. 5,854,067 38. 5,814,500 39. 5,811,300 30. 5,811,275 31. 5,837,510 32. 5,824,519 33. 5,712,257 34. 5,639,655 35. 5,635,385 36. 5,616,459 37. 5,574,142 38. 5,525,468 39. 5,496,698 30. 5,246,921 31. 5,225,347 32. 5,112,734 ATENT DOCUMENTS Document No.	Aug. 8, 2000 28. 6,100,087 Aug. 8, 2000 29. 6,107,094 Aug. 22, 2000 30. 5,968,737 Nov. 16, 1999 31. 5,985,620 Nov. 16, 1999 32. 5,908,779 June 1, 1999 33. 5,898,031 Apr 27, 1999 34. 5,891,717 Apr. 6, 1999 35. 5,866,701 Feb. 2, 1999 36. 5,864,028 Jan. 26, 1999 37. 5,854,067 Dec. 29, 1998 38. 5,814,500 Nov. 1998 39. 5,811,300 Nov. 22, 1998 30. 5,811,275 Nov. 22, 1998 31. 5,837,510 Nov. 17, 1998 32. 5,824,519 Oct. 20, 1998 33. 5,712,257 Jan. 1998 34. 5,639,655 June 17, 1997 35. 5,635,385 June 3, 1997 36. 5,616,459 Apr. 1, 1997 37. 5,574,142 Nov. 12. 1996 38. 5,225,468 June 11, 1996 39. 5,496,698 Mar. 5, 1996 39. 5,246,921 Sep. 21, 1993 31. 5,225,347 July 6, 1993 32. ATENT DOCUMENTS Document No. Publication Date 33. DE 101 00 586 C1 April 11, 2002 34. WO 03/080807 A2 Oct. 2, 2003	27.         6,100,087         Aug. 8, 2000         Rossi, et al.           28.         6,100,444         Aug. 8, 2000         Frelinger, et al.           29.         6,107,094         Aug. 22, 2000         Crooke           30.         5,968,737         Nov. 16, 1999         Ali-Osman, et al.           31.         5,985,620         Nov. 16, 1999         Sioud           32.         5,908,779         June 1, 1999         Crooke           33.         5,898,031         Apr 27, 1999         Newgard, et al.           34.         5,891,717         Apr. 6, 1999         Newgard, et al.           35.         5,866,701         Feb. 2, 1999         Hampel, et al.           36.         5,864,028         Jan. 26, 1999         Sioud           37.         5,854,067         Dec. 29, 1998         Newgard, et al.           38.         5,814,500         Nov. 1998         Dietz           39.         5,811,300         Nov. 22, 1998         Wong-Staal, et al.           40.         5,811,275         Nov. 22, 1998         Wong-Staal, et al.           41.         5,837,510         Nov. 17, 1998         Goldsmith, et al.           42.         5,824,519         Oct. 20, 1998         Norris, et al. <td>  Aug. 8, 2000   Rossi, et al.    </td> <td>  Aug. 8, 2000   Rossi, et al.    </td> <td>  Aug. 8, 2000   Rossi, et al.                                      </td>	Aug. 8, 2000   Rossi, et al.	Aug. 8, 2000   Rossi, et al.	Aug. 8, 2000   Rossi, et al.

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	PATEMI 56.	WO 03/074654 A2	Sep. 12, 2003	PCT	C12N		X	
	57.	WO 03/070972 A2	Aug. 28, 2003	PCT	C12		X	
	58.	WO 03/070969 A2	Aug. 28, 2003	PCT	C12Q		X	
	59.	WO 03/070750 A2	Aug. 28, 2003	PCT	C07K		X	
	60.	WO 03/070283 A2	Aug. 28, 2003	PCT	A61K	48/00	X	
	61.	WO 03/016572 A1	Feb. 27, 2003	PCT	C12Q	1/68	X	
	62.	WO 03/012052 A2	Feb. 13, 2003	PCT	C12N		X	
	63.	WO 02/068637 A2	Sep. 6, 2002	PCT	C12N	15/11	X	
	64.	WO 02/068635 A2	Sep. 6, 2002	PCT	C12N	15/11	X	
	65.	WO 02/44321 A2	Jun. 6, 2002	PCT	C12N		Х	
	66.	WO 02/26780 A2	Apr. 4, 2002	PCT	C07K	14/00	X	
	67.	WO 01/75164 A2	Oct. 11, 2001	PCT	C12Q	1/68	X	
	68.	WO 00/68374	Nov. 16, 2000	PCT	C12N	15/11	X	
	69.	WO 00/63364	Oct. 26, 2000	PCT				
	70.	WO 00/44895	Aug. 3, 2000	PCT	C12N	15/11		X
	71.	WO 00/44914	Aug. 3, 2000	PCT				
	72.	WO 00/01846	Jan. 13, 2000	PCT			-	
	73.	WO 99/61631	Dec. 2, 1999	PCT				
	74.	WO99/53050	Oct. 21, 1999	PCT				
	75.	WO 99/49029	Sept. 30, 1999	PCT				
	76.	WO 99 32619	July 1, 1999	PCT				
	77.	WO 99/15682	Apr. 1, 1999	PCT				
	78.	WO 98/53083	Nov. 26, 1998	PCT				
	79.	DE 196 31 919 C2	July 1998	DE		;	X	
	80.	DE 196 18 797 C2	Nov. 13, 1997	DE				X
	81.	DE 196 18 797 A1	Oct. 1996	DE			Х	
	82.	WO94/01550	Jan. 20, 1994	PCT				
OTHER DO	OCUM	ENTS (including Auth	or, Title, Date, Pertin	ent Pages, etc.)		· · · · · · · · · · · · · · · · · · ·		
	83.	Agrawal et al., 1995, 105-21, Editors: Akhtar, Saghir, Publisher CRC						
	84.	Ambros, V., (2001), "Dicing Up RNAs", Science, 293:811-813.						
	85.	Asanuma, H. et al., (1999), "Photoregulation der Bildung und Dissoziation eines DNA-Duplexes durch cis-trans-Isomerisierung einer Azobenzoleinheit", Angew. Chem., 111:2547-2549.						
	86.	Ausubel, F. et al. (19						

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	PATENT & T
87	Azhayeva, E. et al., (1997), "Inhibitory properties of double helix forming circular oligonucleotides", <i>Nucl. Acids Res.</i> , 25:4954-4961.
88	Bahramian et al.; MOLECULAR AND CELLULAR BIOLOGY, Vol. 19:274 - 283, "Transcriptional and Posttranscriptional Silencing of Rodent α1(I) Collagen by a Homologous Transcriptionally Self-Silenced Transgene Jan. 1999
89	Barwkar, D.A. et al.; Proc. Natl. Acad. Sci USA, Vol. 95:11047 – 11052, September 1998, Chemistry, Biochemistry
90	Bass, B.L., (2000), "Double-Stranded RNA as a Template for Gene Silencing", Cell, 101:235-238.
91	. Bhan et al., Nucleic Acid Research, 1997; Vol. 25; p. 3310
92	. Billy, et al. (2001) PNAS 98(25):14428-33
93	. Borecky et al. (1981-82) Tex Rep Biol Med 41:575-81 Abstract Only
94	Castelli, J. et al., (998), "The 2-5A system in viral infection and apoptosis", <i>Biomed. Pharmacother.</i> , 52:386-390.
95	Cobaleda, C. et al., (2000), "In vivo inhibition by a site-specific catalytic RNA subunit of Rnase P designed against the BCR-ABL oncogenic products: a novel approach for cancer treatment", <i>Blood</i> , 95(3):731-737.
96	Datenbank MEDLINE bei STN: AN 1999091059 MEDLINE; DN 99091059 zu: Use of dsRNA-mediated genetic interference to demonstrate that frizzled and frizzled 2 act in the wingless pathway. Kennerdell J.R.; Carthew R.W.; CELL, (1998 Dec. 23) 95(7):1017-1026.
97	Downward, J. et al., (1990), "Identification of a nucleotide exchange-promoting activity for p21 <sup>ras</sup> ", <i>Proc. Natl. Acad. Sci. USA</i> ", 87:5998-6002.
98	. Elbashir, et al. (2001) Nature 411:494-498
99	. Fire, 9/99, RNA-triggered gene silencing, Trends Genet, 15: 358-363.
100	Fire, A., et al., 1991, Production of Antisense RNA leads to effective and specific inhibition of gene expression in C. elegans muscle, Development 113: 503-514
10	Gautschi, O. et al., (2001), "Activity of a Novel bel-2/bel-xL-Bispecific Antisense Oligonucleotide Against Tumors of Diverse Histologic Origins", <i>Journal of the National Cancer Institute</i> , 93(6):463-471.
102	2. Gibbs, J.B. et al., (1988), "Purification of ras GTPase activating protein from bovine brain", <i>Proc. Natl. Acad. Sci. USA</i> ", 85:5026-5030.
103	3. Grasby, JA et al.; Biochemistry 1995 Mar 28; 34(12);4068 – 76
104	Griffey, RH et al.; J Med Chem 1996 Dec 20; 39(26);5100-9
10:	5. Ha, I et al.; Genes Dev 1996 Dec 1;10(23);3041-50
100	Hamilton et al.; SCIENCE, Vol. 286:950 - 951, "A Species of Small Antisense RNA in Posttranscriptional Gene Silencing in Plants (Oct. 29, 1999)
107	Hammond, S.M. et al., (2000), "An RNA-directed nuclease mediates post-transcriptional gene silencing in <i>Drosophila</i> cells", <i>Nature</i> , 404:293-296.
108	B. Hoke, GD et al.; Nucleic Acids Res 1991 Oct 25; 19(20):5743-8



109.	Holen, T. et al., (2002), "Positional effects of short interfering RNAs targeting the human coagulation trigger Tissue Factor", <i>Nucleic Acids Research</i> , 30(8):1757-1766.
110.	Horn, T et al.; Nucleic Acids Research, 1997, Vol. 25, No. 23: 4842 – 4849
111.	Hunter, 6/17/99, A touch of elegance with RNAi, Curr Biolo, 9: R440-R442
112.	Iwase, R et al.; Nucleic Acids Symp Ser 1997; (37);203 – 4
113.	Jacobs, B.L., and Langland, J.O., 1996, When two stands are better than one: The mediators and modulators of the cellular responses to double-stranded RNA. Virology 219: 339-349
114.	Kennerdell et al.; CELL, Vol. 95, S. 1017 – 1026; "Use of dsRNA-Mediated Genetic Interference to Demonstrate that frizzled and frizzled 2 Act in the Wingless Pathway" Dec 23, 1998
115.	Klemens, et al.(1999), The 2 Å Structure of helix 6 of the human signal recognition particle RNA., Structure 7(11): 1345-1352
116.	Kreutzer et al (1999) Gesellschaft fur Biochemie und Molekularbiologie S169
117.	Lee, et al.; CELL, Vol. 88; S. 637 – 646; March 7, 1997; "The Cold Shock Domain Protein LIN-28 Controls Developmental Timing in C. elegans and Is Regulated by the lin-4 RNA
 118.	Li et al., Dev. Biology Volume 210, 1999, p. 238 abstract 346
 119.	Lin et al.; NATURE, Vol. 402:128 - 129, "Policing rogue genes" Nov. 11, 1999
 120.	Lipardi, C. et al., (2001), "RNAi as Random Degradative PCR: siRNA Primers Convert mRNA into dsRNAs that Are Degraded to Generate New siRNAs", <i>Cell</i> , 107:297-307.
 121.	Lipinski, et al. (1997) Adv. Drug Delivery Review 23:3-25
 122.	Lowy, D.R. et al., (1993), "Function and Regulation of RAS", Annu. Rev. Biochem., 62:851-891.
 123.	Ma MY (1993) Biochem. 32(7):1751-8
124.	Majumdar, A et al.; Nat Genet 1998 Oct; 20(2):212-4
125.	Milhaud et al., Journal of Interferon Research, 1991, vol. 11, 261-265
 126.	Minks, M. A. et al., The Journal of Biological Chemistry (1979), 254, (20):10180 – 10183
 127.	Montgomery, M., and Fire, 1998, Analysis of a Caenorhabditis elegans twist homolog identifies conserved and divergent aspects of mesodermal patterning, Genes and Development, 12: 2623-2635.
128.	Montgomery M.K., et al., 1998, RNA as a target of double-stranded RNA-mediated genetic interference in Caenorhabditis elegan, Proc. Natl. Acad. Sci. 95: 15502-15507.
129.	Montgomery, et al., July 1998, Double-stranded RNA as a mediator in sequence-specific genetic silencing and co-suppression, TIG, Vol. 14, No. 7., pgs. 255-258
130.	Misquitta, L. and Paterson, B.M., 1999, Targeted disruption of gene function in Drosophila by RNA interference (RNA-i): A role for nautilus in embryonic somatic muscle formation, Proc. Natl. Acad. Sci. 96: 1451-1456
 131.	Neilsen et al. (1997) Chem. Comm. 825-826
132.	Ngo, H., et al., 1998, Double-stranded RNA induces mRNA degradation in Trypanosoma brucei, Proc. Natl. Acad. Sci. 95: 14687-14692.
133.	Nikiforov, et al. (1992) Nucleic Acids Research 20(6):1209-1214